

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re U.S. Patent No. 7,351,875

Inventors: HOGARTH et al.

Issued: April 1, 2008

Atty. File No.: 5644AL-1

For: FcγRIIA TRANSGENIC ANIMAL MODEL  
FOR AUTOIMMUNE DISEASE"

} Application No.: 10/517,251

} Group Art Unit: 1633

} Examiner: Wehbé, A.M.S.

} Conf. No.: 2961

} REQUEST FOR  
CERTIFICATE OF CORRECTION

ATTN: Certificate of Correction Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 35 U.S.C. § 254 and 37 C.F.R. § 1.322, this is a request for a Certificate of Correction in the above-identified patent. The mistakes identified in the appended Form PTO/SB/44 resulted from errors made by the Office, and thus no fee is believed due in connection with this Request.

The above-identified patent was printed by the Office without including the claims amended and added by the Examiner's amendment included in the Notice of Allowance/Notice of Allowability dated November 23, 2007. A copy of this Notice of Allowance/Notice of Allowability is enclosed herewith.

Accordingly, numerous corrections to claims 1-3, 5 and 6 are set forth on the appended Form PTO/SB/44. In addition, claims 43-52 were allowed by the Examiner in the Notice of Allowance/Notice of Allowability dated November 23, 2007, but omitted from the above-referenced patent as printed by the Office. Allowed claims 43-52, renumbered in accordance with Office practice as claims 9-18, are also included on the appended Form PTO/SB/44.

The complete Certificate of Correction involves three (3) pages. Issuance of the Certificate of Correction containing the corrections set forth in the appended form is earnestly requested.

Alternatively, considering the extent of the errors in the printed patent, the Assignee hereby requests that the Office reissue or reprint the above-referenced patent

in its entirety or take whatever remedial action the Office deems appropriate to provide adequate notice of the patent's true claims to the public.

If any questions arise regarding this paper, please contact the undersigned at 303-863-9700. In the event that any fees are due in connection with this paper, please debit Deposit Account No. 19-1970.

Respectfully submitted,

SHERIDAN ROSS P.C.

Dated: May 15, 2008

By: /John C. Stolpa/  
John C. Stolpa  
Registration No. 57,632  
1560 Broadway, Suite 1200  
Denver, CO 80202-5141  
(303) 863-9700

## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 3

PATENT NO. : 7,351,875  
APPLICATION NO.: 10/517,251  
ISSUE DATE : April 1, 2008  
INVENTOR(S) : Hogarth et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

**Column 24:**

Line 28, please delete ", aberrant immune complex clearance".  
Line 31, please insert -- a -- between "to" and "transgenic".  
Line 37, please insert -- receptor -- between "FcγRIIa" and "renders".  
Line 38, please insert -- spontaneous development of -- prior to "an autoimmune".  
Lines 38-40, please delete "caused by aberrant immune complex formation, aberrant immune complex clearance or immune complex induced inflammation" and insert  
-- selected from the group consisting of arthritis and systemic lupus erythematosus -- in its place.  
Line 42, please insert -- said -- between "reduces" and "aberrant".  
Line 42, please insert -- associated with arthritis or systemic lupus erythematosus -- between "activity" and "in".  
Line 43, please delete "," and insert -- . --.  
Lines 44-46, please delete "wherein said autoimmune disease is selected from the group consisting of arthritis and systemic lupus erythematosus."  
Line 47, please delete "of" and insert -- for -- in its place.  
Lines 49-50, please delete "complex formation, aberrant immune complex clearance or immune complex induced inflammation" and insert -- activity -- in its place.  
Line 52, please delete ", aberrant immune complex clearance".  
Line 61, please insert -- receptor -- between "FcγRIIa" and "renders".  
Line 62, please insert -- spontaneous development of -- prior to "an autoimmune".  
Lines 62-64, please delete "caused by aberrant immune complex formation, aberrant immune complex clearance or immune complex induced inflammation" and insert  
-- selected from the group consisting of arthritis and systemic lupus erythematosus -- in its place.  
Line 66, please insert -- said -- between "reduces" and "aberrant".  
Line 66, please insert -- associated with arthritis or systemic lupus erythematosus -- between "activity" and "in".  
Line 67, please delete "," and insert -- . --.

**MAILING ADDRESS OF SENDER (Please do not use customer number below):**

Sheridan Ross P.C.  
1560 Broadway, Suite 1200  
Denver, CO 80202

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 2 of 3

PATENT NO. : 7,351,875  
APPLICATION NO.: 10/517,251  
ISSUE DATE : April 1, 2008  
INVENTOR(S) : Hogarth et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

**Column 25:**

Lines 1-3, please delete "wherein said autoimmune disease is selected from the group consisting of arthritis and systemic lupus erythematosus".

Lines 6-7, please delete "complex formation, aberrant immune complex clearance or immune complex induced inflammation" and insert -- activity -- in its place.

Line 19, please insert -- receptor -- between "FcγRIIa" and "renders".

Line 19, please insert -- spontaneous development of -- between "to" and "an".

Line 20, please delete "caused by aberrant immune complex" and insert -- selected from the group consisting of arthritis and systemic lupus erythematosus -- in its place.

**Column 26:**

Lines 1-2, please delete "formation, aberrant immune complex clearance or immune complex induced inflammation".

Line 3, please insert -- said -- after "reduces".

Line 4, please insert -- associated with arthritis or systemic lupus erythematosus -- between "activity" and "in".

Line 10, please delete "rodent" and insert -- mouse -- in its place.

Lines 13-14, please delete "an autoimmune disease" and insert -- arthritis or systemic lupus erythematosus -- in its place.

**MAILING ADDRESS OF SENDER (Please do not use customer number below):**

Sheridan Ross P.C.  
1560 Broadway, Suite 1200  
Denver, CO 80202

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 3 of 3

PATENT NO. : 7,351,875  
APPLICATION NO.: 10/517,251  
ISSUE DATE : April 1, 2008  
INVENTOR(S) : Hogarth et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 26:

Line 19, please insert the following ten (10) claims:

- 9. A method according to claim 2, wherein the method comprises assessing the transgenic mouse to determine if the compound reduces immune complex induced inflammation.  
10. A method according to claim 2, wherein the compound reduces aberrant immune activity in the transgenic mouse by inhibiting the activity of human FcγRIIa receptor expressed in the mouse.  
11. A method according to claim 2, wherein in step (b) the aberrant immune activity is assessed in terms of clinical symptoms and/or pathological features of arthritis or systemic lupus erythematosus.  
12. A method according to claim 2, wherein the autoimmune disease is rheumatoid arthritis (RA).  
13. A method according to claim 2, wherein the autoimmune disease is collagen-induced arthritis (CIA).  
14. A method according to claim 3, wherein the method comprises assessing the cell to determine if the compound reduces immune complex induced inflammation.  
15. A method according to claim 3, wherein the compound reduces aberrant immune activity in the cell by inhibiting the activity of human FcγRIIa receptor expressed in the cell.  
16. A method according to claim 3, wherein in step (b) the aberrant immune activity is assessed in terms of clinical symptoms and/or pathological features of arthritis or systemic lupus erythematosus.  
17. A method according to claim 3, wherein the autoimmune disease is rheumatoid arthritis (RA).  
18. A method according to claim 3, wherein the autoimmune disease is collagen-induced arthritis (CIA). --

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Sheridan Ross P.C.  
1560 Broadway, Suite 1200  
Denver, CO 80202

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

22442 7590 11/23/2007  
SHERIDAN ROSS PC  
1560 BROADWAY  
SUITE 1200  
DENVER, CO 80202

EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	
DATE MAILED: 11/23/2007	

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,251	12/07/2004	Phillip Mark Hogarth	5644AL-1	2961

TITLE OF INVENTION: FCYRIIA TRANSGENIC ANIMAL MODEL FOR AUTOIMMUNE DISEASE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	02/25/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.
- B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
or Fax (571)-273-2885**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

22442 7590 11/23/2007

SHERIDAN ROSS PC  
1560 BROADWAY  
SUITE 1200  
DENVER, CO 80202

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/517,251 12/07/2004 Phillip Mark Hogarth 5644AL-1 2961

TITLE OF INVENTION: FCYRIIA TRANSGENIC ANIMAL MODEL FOR AUTOIMMUNE DISEASE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	02/25/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
WEHBE, ANNE MARIE SABRINA	1633	800-003000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,251	12/07/2004	Phillip Mark Hogarth	5644AL-1	2961
22442	7590	11/23/2007	EXAMINER	
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			WEHBE, ANNE MARIE SABRINA	
			ART UNIT	PAPER NUMBER
			1633	
DATE MAILED: 11/23/2007				

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.



**Notice of Allowability**

Application No.

10/517,251

Examiner

Anne Marie S. Wehbe

Applicant(s)

HOGARTH ET AL.

Art Unit

1633

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the after-final amendment received on 8/10/07.
2. ☒ The allowed claim(s) is/are 1-3,5,8,9,11,12 and 43-52.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                                 |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|  | 9. <input type="checkbox"/> Other _____.  |

### **ATTACHMENT TO ALLOWANCE**

Applicant's after-final amendment received on 8/10/07 has been entered. Claims 4, 6-7, 10, and 13-42 are canceled. Claims 1-3, 5- 8-9, and 11-12 were pending following entry of the after-final amendment.

#### ***Interviews***

The applicant originally contacted the examiner to inquire after the after-final amendment filed on 8/10/07. The examiner determined that the document has not been entered into the PALM system and requested immediate entry of the document. The case was then forwarded to the examiner on 10/22/07. After consideration of the amendment, the examiner contacted the applicant's representative on 10/30/07 to discuss potential claim amendments to place the application in condition for allowance. The applicant's representative provided the examiner with a proposed draft amendment of the claims on 11/3/07. The examiner again contacted the applicant's representative on 11/5/07 to discuss the draft amendment. On 11/8/07, agreement was reached and the examiner agreed to make the amendments to the claims via examiner's amendment to place the application in condition for allowance.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Darla Yoerg on 11/8/07.

The application has been amended as follows:

1. Claim 1 has been rewritten as follows:

1. A method for screening a compound that is able to suppress aberrant immune activity, wherein the aberrant immune activity is selected from aberrant immune complex formation and immune complex induced inflammation, the method comprising the steps of:

- a. administering a compound to be screened to a transgenic mouse generated by transgenically modifying an embryo from a strain, derived from strains C57BL/6 and SJL, that is resistant to collagen-induced arthritis, such that said mouse comprises and expresses a transgene for human FcγRIIa receptor, whereby the expression of said FcγRIIa receptor renders the mouse susceptible to spontaneous development of an autoimmune disease selected from the group consisting of arthritis and systemic lupus erythematosus; and
- b. assessing the transgenic mouse to determine if the compound reduces said aberrant immune activity associated with arthritis or systemic lupus erythematosus in the mouse.

2. Claim 2 has been rewritten as follows:

2. A method for screening a compound that is able to suppress an autoimmune disease caused by aberrant immune activity by suppressing aberrant immune activity selected from aberrant immune complex formation and immune complex induced inflammation, the method comprising the steps of:

- a. administering a compound to be screened to a transgenic mouse generated by transgenically modifying an embryo from a strain, derived from strains C57BL/6 and SJL, that is resistant to collagen-induced arthritis, such that said mouse comprises and expresses a transgene for human FcγRIIa receptor, whereby the expression of said FcγRIIa receptor renders the mouse susceptible to spontaneous development of an autoimmune disease selected from the group consisting of arthritis and systemic lupus erythematosus; and
- b. assessing the transgenic mouse to determine if the compound reduces said aberrant immune activity associated with arthritis or systemic lupus erythematosus in the mouse.

3. Claim 3 has been rewritten as follows:

3. A method for screening a compound that is able to suppress an autoimmune disease caused by aberrant immune activity, the method comprising the steps of:

- a. administering a compound to be screened to a non-human cell expressing human FcγRIIa receptor, wherein the cell is selected from the group consisting of platelets, neutrophils, and macrophages, and wherein the cell is derived from a transgenic mouse generated by transgenically modifying an embryo from a strain, derived from strains

C57BL/6 and SJL, that is resistant to collagen-induced arthritis, such that said mouse comprises and expresses a transgene for human FcγRIIa receptor, whereby the expression of said FcγRIIa receptor renders the mouse susceptible to spontaneous development of an autoimmune disease selected from the group consisting of arthritis and systemic lupus erythematosus; and

b. assessing the cell to determine if the compound reduces said aberrant immune activity associated with arthritis or systemic lupus erythematosus in the cell.

4. In claim 8, line 3, the word “rodent” has been replaced by the word - - mouse--.

5. In claim 9, line 3 the phrase “an autoimmune disease” has been replaced by - - arthritis or systemic lupus erythematosus - -.

6. New claims 43-52 have been added as follows:

43. A method according to claim 2, wherein the method comprises assessing the transgenic mouse to determine if the compound reduces immune complex induced inflammation.

44. A method according to claim 2, wherein the compound reduces aberrant immune activity in the transgenic mouse by inhibiting the activity of human FcγRIIa receptor expressed in the mouse.

45. A method according to claim 2, wherein in step (b) the aberrant immune activity is assessed in terms of clinical symptoms and/or pathological features of arthritis or systemic lupus erythematosus.

46. A method according to claim 2, wherein the autoimmune disease is rheumatoid arthritis (RA).

47. A method according to claim 2, wherein the autoimmune disease is collagen-induced arthritis (CIA).

48. A method according to claim 3, wherein the method comprises assessing the cell to determine if the compound reduces immune complex induced inflammation.

49. A method according to claim 3, wherein the compound reduces aberrant immune activity in the cell by inhibiting the activity of human FcγRIIIa receptor expressed in the cell.

50. A method according to claim 3, wherein in step (b) the aberrant immune activity is assessed in terms of clinical symptoms and/or pathological features of arthritis or systemic lupus erythematosus.

51. A method according to claim 3, wherein the autoimmune disease is rheumatoid arthritis (RA).

52. A method according to claim 3, wherein the autoimmune disease is collagen-induced arthritis (CIA).

Following entry of this examiner's amendment, the rejections of the previously pending claims under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 103(a) have been withdrawn.

Claims 1-3, 5, 8-9, 11-12, and 43-52 are pending and allowed.

The following is an examiner's statement of reasons for allowance: the amendment the claims limiting the transgenic mouse to a strain derived from strains C57BL/6 and SJL overcomes the previously pending rejection of the claims under 35 U.S.C. 112, first paragraph, for scope of enablement. Further, the amendment of the claims to indicate that the transgenic mouse spontaneously develops arthritis and systemic lupus erythematosus and that the assessing step determines if the compound reduces aberrant immune activity associated with arthritis or systemic lupus erythematosus overcomes the rejection of the claims under 35 U.S.C. 103(a) based on the teachings of McKenzie et al. It is noted that while McKenzie et al. teaches a mouse with the same structure as that in the claims, McKenzie et al. only teaches assessing immune complex clearance associated with thrombocytopenia and does not teach or suggest assessing aberrant immune activity, and in particular aberrant immune complex formation and immune complex induced inflammation, associated with arthritis or systemic lupus erythematosus

Art Unit: 1633

because McKenzie et al. did not recognize that the transgenic mice spontaneously develop arthritis and systemic lupus erythematosus as they age. Therefore, neither McKenzie et al. nor remaining prior art of record provide teachings or motivation for using the transgenic mice or cells derived from the transgenic mouse as claimed to test for compounds capable of suppressing aberrant immune activity associated with arthritis or systemic lupus erythematosus.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your



Application/Control Number: 10/517,251

Page 9

Art Unit: 1633

application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

*/Anne Marie S. Wehbé/*

Primary Examiner, A.U. 1633